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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/593,288	06/13/00	STEIN	<sup>ID</sup> B 860098.403C1

000500 HM22/0402  
SEED INTELLECTUAL PROPERTY LAW GROUP PLL  
701 FIFTH AVE  
SUITE 6300  
SEATTLE WA 98104-7092

EXAMINER  
PAK, Y

ART UNIT	PAPER NUMBER
1652	<sup>ID</sup>

DATE MAILED: 04/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/593,288

Applicant(s)

STEIN ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1 and 4-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application is continuation of 08/576240, issued as U.S. Patent 6,074,862 on June 13, 2000. A preliminary amendment filed on September 12, 2000, canceling claims 2-3 and amending the claims, has been entered.

Claims 1 and 4-21 are pending.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to protein kinase, classified in class 435, subclass 194.
- II. Claims 4-7, drawn to DNA encoding protein kinase, vector comprising said DNA, and a host cell transformed thereof, classified in class 435, subclass 252.3.
- III. Claim 8, drawn to a method of activating p38, classified in class 435, subclass 41.
- IV. Claims 9-10, drawn to a method of treatment by activating p38, classified in class 424, subclass 94.5.
- V. Claims 11-12 and 18-20, drawn to a method for screening an agent that inhibits/stimulates phosphorylation of p38 classified in class 435, subclass 15.
- VI. Claims 13-14, drawn to antibodies against protein kinase, classified in class 530, subclass 387.9.
- VII. Claims 15-16, drawn to a method of treatment with an antibody, classified in class 424, subclass 130.1.

VIII. Claims 15 and 17, drawn to a method of treatment with nucleic acids, classified in class 514, subclass 44.

IX. Claims 21, drawn to a method of treatment with a modulator, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and VI are patentably distinct because a protein, a DNA and an antibody, are different compounds, each with its own chemical structure and function, and they have different utilities. A DNA molecule of inventions I is not limited in use to the production of polypeptide of invention I and can be used as a hybridization probe, and protein of invention II can be obtained by a materially different method such as by biochemical purification. The structure of an antibody of Invention VI is not predictable from the structure of the protein of invention I and an antibody can cross-react with various proteins.

Invention (I and III), (I and IV) and (I and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of Invention I can be used for the production of antibodies, in the method of activating p38 of Invention III, in an in vivo method of treatment of Invention IV, and in an method for screening inhibitors/stimulators of phosphorylation of p38 of Invention V.

The methods of Inventions III and VII-IX are methods of treatment and are patentably distinct as employing different products. Inventions III uses polypeptide, Invention VII uses antibodies, Invention VIII uses nucleic acids, and Invention IX uses an unknown compound. Invention III and Inventions IV-V, in vitro methods, are patentably distinct from each other because the methods have different effects and utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Anthony Insogna on March 15, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Drawings***

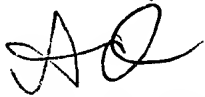
Drawings filed concurrently with the application have been approved by the Draftsman.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISOR  
TECHNICAL STAFF

March 26, 2001